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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/994,320	11/26/2001	Teodulo Aves	06570/002002	1358

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EXAMINER

LAM, ANN Y

ART UNIT	PAPER NUMBER
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3763

DATE MAILED: 07/05/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

7e

Office Action Summary	Application N . 09/994,320	Applicant(s) A	
	Examiner Ann Y. Lam	Art Unit 3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-21 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-21 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4. 6) ☐ Other:

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

1. Claims 1-6, 8-15 and 18 are rejected under 35 U.S.C. 102(e) as being anticipated by McKernan et al., 6,283,948. McKernan et al. discloses a needle (20) wherein the cutting surface (60) is on the bottom of the hollow shaft of the needle.

As to claim 2, the cutting surface (60) is from the bottom of the distal end of the hollow shaft to the front of the distal end of the hollow shaft.

As to claim 3, the needle (20) is adapted to be used where the cutting surface is substantially parallel to the dural fibers.

As to claim 4, the sharpness of the cutting surface is considered to be, as measured by the grams of force required for the needle tip to puncture a sheet of two

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mil thick polyethylene, is from about 85 grams of force to about 100 grams of force, see column 2, lines 17-19.

As to claims 5, 6, 11, 12, the needle is adapted to used in the procedures claimed.

As to claim 9, the cutting surface (60) begins on the bottom of the distal end of the hollow shaft and ends on the front of the distal end of the hollow shaft.

As to claim 10, McKernan et al. discloses a solid rod (340) having opposed proximal and distal ends, the distance between the opposed ends of the solid rod being substantially the same as the distance between the proximal end of an adapter attached to the needle and the distal tip of the needle shaft, the proximal end of the solid rod being secured to a gripping means (100) for holding the rod, the rod being insertable through the proximal end of the adapter such that when the gripping means abuts the proximal end of the adapter, the distal end of the rod extends within the opening in the needle shaft, wherein the rod is adapted to prevent tissue debris from clogging the lumen during introduction of the needle into a patient's body.

As to claim 13, a beveled surface is disclosed at (60), wherein the beveled surface is rounded and extends from the distal end of the cutting surface on the bottom of the shaft to the opening of the lumen on the top of the shaft.

As to claim 14, the beveled surface has a radial length less than about 25% of the needle outside diameter.

As to claim 15, the cutting surface (60) has the shape of a hull and extends from the outer edge of the bottom of the needle shaft to the front of the distal end of the shaft.

2. Claims new 16, 17, 18, 20 and 21 are rejected under 35 U.S.C. 102(e) as being anticipated by Gross, 4,781,691. Gross discloses a method comprising the steps of: pushing a needle (10) into the epidural space with a cutting surface of the needle substantially parallel to the dura fibers of a patient, (see column 4, lines 34-33, wherein the needle comprises a substantially straight cutting surface; feeding a catheter (34) through the needle and into the epidural space, see column 4, lines 39-43; removing the needle, while holding the catheter stationary; see column 4, lines 54-56, and securing the catheter, see column 4, lines 60-64.

As to claim 18, the cutting surface of the needle (10) comprises an axial component that is within about thirty degrees of parallel to the longitudinal axis of the shaft of the needle, see Figure 6.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over McKernan et al., 6,283,948

McKernan et al. discloses the invention substantially as claimed, see above.

However, McKernan et al. does not disclose that the needle is about 12 gauge to about

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16 gauge. McKernan et al. however teaches that the disclosed device can be used to introduce a surgical instrument into a body cavity or joint, see column 1, lines 30-31.

Thus, it would have been obvious to one of ordinary skill in the art at the time the invention was made to form the McKernan et al. needle in the dimensions as claimed, as necessary to perform surgery in a particular body cavity or joint.

4. ^{1.9} Claim ~~7~~ is rejected under 35 U.S.C. 103(a) as being unpatentable over McKernan et al., 6,283,948, in view of Takai et al., 4,945,895. McKernan et al. discloses the invention substantially as claimed, see above. However, McKernan et al. does not disclose a camera inside the lumen of the needle.

Takai et al. discloses a fiber optic (30) inside a needle for visualization during surgery. The fiber optic is equivalent to a camera as claimed. It would have been obvious to provide the fiber optic in the lumen of the McKernan needle for visualization during surgery as taught by McKernan et al.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ann Y. Lam whose telephone number is (703) 306-5560. The examiner can normally be reached on T-F 8-6:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on (703)308-3552. The fax phone numbers for

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the organization where this application or proceeding is assigned are (703)305-3590 for regular communications and (703)306-4520 for After Final communications.

A.L.

June 30, 2002


ANH TUAN T. NGUYEN
PRIMARY EXAMINER

7/1/02